DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 22, 2015

Jintronix Inc.
c/o Navneet Sekhon
AxSource Consulting Inc.
336 Bronte Street South, Suite 224-225
Milton, Ontario L9T 7W6

Re: K143034
Trade/Device Name: Jintronix Version 2.0
Regulatory Class: Unclassified
Product Code: LXJ
Dated: March 19, 2015
Received: March 20, 2015

Dear Ms. Sekhon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143034

Device Name
Jintronix Version 2.0

Indications for Use *(Describe)*
Jintronix is a software system used with the Microsoft Kinect v2 intended to be used to support the physical rehabilitation of adults in the clinic/ at home. The system includes rehabilitation exercises for the upper extremity, trunk, and lower extremity with audio-visual feedback & graphic movement representations for patients as well as remotely accessible patient performance metrics for the medical professional. Patient assessment, exercise guidance and approval by the medical professional is required prior to use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

7. 510(k) Summary

7.1 Owner Information

Name:	Jintronix Inc.
Device common name:	System, optical position/movement recording
Address:	999 3rd Avenue, Suite 3400, Seattle, WA 98104
Phone:	1-514-754-6688
Fax:	*None*
Contact:	Mark Evin
Title:	Regulatory Affairs & Quality Assurance Head (RAQA)
Email:	mark@jintronix.com
Date of Preparation:	March 13, 2015

7.2 Regulatory Correspondent Information

Name:	AxSource Consulting Inc.
Address:	336 Bronte Street South, Suite 224-225 Milton, Ontario, L9T 7W6
Office Phone:	905-854-6059
Contact Person:	Ms. Navneet Sekhon, President
Email:	nav.sekhon@axsource.ca

7.3 Device Information

Trade Name	Jintronix
Common Name	System, optical position/movement recording
Classification name	System, optical position/movement recording
Model Number	Version 2.0.140905
510(k) Submitter / Holder	Jintronix Inc.
Device Panel	Physical Medicine
Product Code	LXJ
Classification Regulation	Unclassified

7.4 Predicate(s) / Substantially Equivalent Device(s)

General 510(k) information	Predicate Device(s) [510(k) summaries attached – Appendices 6 & 7]	
Trade Name	Jintronix	Peak Motus Motion Measurement System
Model Number	Version 1.0	Unknown

General 510(k) information	Predicate Device(s) [510(k) summaries attached – Appendices 6 & 7]	
510(k) Submitter / Holder	Jintronix Inc.	Peak Performance Technologies Inc.
510(k) Number	K130847	K030714
Device Panel	Physical Medicine	Physical Medicine
Product Code	LXJ	LXJ

7.5 Device Description

Jintronix Version 2.0.140905, a software system comprising of a client application and a web application is to be used with the Microsoft Kinect version 2 to support the physical rehabilitation of adults in the clinic/ at home.

Through the client application, the patient engages in their rehabilitation exercises. Using the Microsoft Kinect for Windows, which tracks the patient's upper extremity, trunk, and lower body joint positions as they move, the software provides a graphic representation of the patient's movements, as well as activities that include visual and audio feedback to support the patient in performing therapeutic exercise.

As the patient engages in exercises, the system records performance metrics, such as the speed and precision of their movements. These metrics are then sent to a remote web application.

Clinicians, through a "clinician interface" of the Client application, securely access the remote web application to remotely monitor the progress of their patients, and modify the exercise program through program customizations (for example, difficulty level) based on patients' needs.

Patient assessment, exercise guidance and approval by the medical professional is required prior to use. There is no direct contact with the patient since the device is a software product. No energy is delivered to the subject.

7.6 Indications for Use

Jintronix is a software system used with the Microsoft Kinect v2 intended to be used to support the physical rehabilitation of adults in the clinic/ at home. The system includes rehabilitation exercises for the upper extremity, trunk, and lower extremity with audio-visual feedback & graphic movement representations for patients as well as remotely accessible patient performance metrics for the medical professional. Patient assessment, exercise guidance and approval by the medical professional is required prior to use.

	Predicate Device(s) [510(k) summaries attached]		Jintronix (v2.0.140905)	Jintronix and Predicate(s) Discussion
	Jintronix Rehabilitation System (JRS)	Peak Motus		
Indications for Use	A software system used with the Microsoft Kinect intended to be used to support the physical rehabilitation of adults in the clinic/ at home. The system includes rehabilitation exercises for the upper extremity and trunk with audio-visual feedback & graphic movement representations for patients as well as remotely accessible patient performance metrics for the medical professional. Patient assessment, exercise guidance and approval by the medical professional is required prior to use. [1]	Computer and video system used to quantify and graphically display human movement patterns and techniques for uses such as assessment and training of limb or body motion in gait analysis, prosthetic design, pre/post rehabilitation evaluation, physical therapy, and the like.[2]	A software system used with the Microsoft Kinect version 2 intended to be used to support the physical rehabilitation of adults in the clinic/ at home. The system includes rehabilitation exercises for the upper extremity, trunk, and lower extremity, with audio-visual feedback & graphic movement representations for patients as well as remotely accessible patient performance metrics for the medical professional. Patient assessment, exercise guidance and approval by the medical professional is required prior to use.	Jintronix shares the same indications for use as the predicates. All devices are intended for physical rehabilitation. All devices include graphic movement representations and performance metrics for assessment. Like the JRS, Jintronix is for clinic/at home physical rehabilitation of the upper extremity and trunk. Like predicate Peak Motus, Jintronix is indicated for limbs and full body. No difference between Jintronix and predicates.

[1] FDA 510(k) Database. *Jintronix Rehabilitation System. 510(k) Summary* (attached). Retrieved August 30, 2014, from http://www.accessdata.fda.gov/cdrh_docs/pdf13/K130847.pdf
[2] FDA 510(k) Database. *Peak Motus Motion Measurement System. 510(k) Summary* (attached). Retrieved September 23, 2014, from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=11114

7.7 Comparison of Technological Characteristics with Predicate Device(s)

Principles of operation and fundamental design and technology considerations are shared by Jintronix and its predicates.

Specifically, Jintronix and its predicate(s)

1. Are software / hardware systems or computer systems using optical capture motion technology
2. Track movement and provide visual feedback or graphic movement representations
3. Report on kinematic parameters or provide performance metrics for assessment
4. Are non-invasive devices and so do not deliver energy to patients
5. Do not pose any issues in terms of electrical, chemical, mechanical, thermal or radiation safety
6. Are non-sterile devices

Jintronix is validated for system compatibility and performance.

The following technological differences exist between Jintronix and its predicates.

1. Jintronix improves usability with its new design features which include enhanced software user interfaces and a simple range of motion assessment feature desired by clinicians.

2. Jintronix surpasses predicate JRS in performance. Jintronix uses the Kinect v2 for optical motion capture. The Kinect v2 is more precise over a greater tracking range than Kinect v1 used with predicate JRS.

7.8 Performance Data

7.8.1 Performance Data Summary / Conclusions

Jintronix system performance is validated as suitable for its indications for use surpassing the performance of predicate JRS. With improved performance accuracy, Jintronix has a better safety and effectiveness profile when compared to predicate JRS.

Jintronix System	Supporting Performance Data	Performance Conclusions & SE Comparison to Predicate(s)
Data Processing Accuracy	1. System Validation	1. Jintronix data processing accuracy verified by software testing. 2. Clinician feedback.
System Compatibility	System Validation (software testing)	System compatibility of Jintronix software, Microsoft Kinect v2 hardware and the recommended computer operating system in Jintronix labeling assured by software testing.
Kinect Performance Accuracy / Effectiveness	Bench Study	Jintronix surpasses predicate JRS in performance. Jintronix uses the Kinect v2 (for optical motion capture) which is more precise over a greater tracking range than Kinect v1 used with predicate JRS. Jintronix can be consistently reproduced within an error tolerance that is comparable to intra-rater precision error[1] of goniometry. Shoulder range of motion measurements can only be used to describe a patient's relative change in joint angle, not absolute joint angle. Shoulder range of motion measurements have not been validated in standardized postures associated with goniometric measurements. Bench study recommendations for optimal performance have been incorporated or accounted for.
Kinect Electrical Safety	Refer to FDA recognized standard and test reports for Class I laser (section 7.8.3 below)	Kinect deemed electrically safe.

7.8.2 System Validation for System Compatibility & Performance Accuracy

Jintronix system accuracy in data processing was validated by software testing. Jintronix software is of "moderate" level of concern. All potential device hazards have been mitigated through appropriate controls. Jintronix software has been validated with Windows Defender, anti-virus software.

Jintronix conforms partially to the following FDA recognized standards and associated FDA guidance documents.

1. Medical device software - Software life cycle processes
   AAMI / ANSI / IEC 62304:2006

[1] Defined as the degree of agreement among repeated administrations of a diagnostic test performed by a single rater

2. Guidance on the use of AGILE practices in the development of medical device software AAMI TIR45:2012
3. Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff, May 2005
4. General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 2002

7.8.3 Electrical Safety

Jintronix is software for use with Microsoft Kinect v2 hardware. The Microsoft Kinect v2 used with Jintronix software is electrically safe. The Kinect for Windows v2 hardware conforms to the International Standard IEC 60825-1:2007:03 for a Class 1 laser product and with 21 CFR 1040.10 & 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

7.8.4 Bench Study - Kinect v2 Performance Accuracy / Effectiveness

Jintronix Inc. commissioned an independent study to determine the performance accuracy of Microsoft Kinect v2, the optical motion capture technology for use with Jintronix. Kinect's accuracy was determined in terms of kinematics over a range of distances between the Kinect and the user. In the study, the Kinect v2 was compared to the Optotrak, a gold standard in motion sensing technology with a reported precision of less than 0.5mm. Kinect v2 performance was compared to that of Kinect v1 and goniometry, the clinical standard for range of motion measurements.

The bench study found that Jintronix range of motion (ROM) assessments using the Kinect v2 can be consistently reproduced within an error tolerance that is comparable to intra-rater precision error[2] of goniometry.

7.9 Other Information

7.9.1 Jintronix Compliance to FDA Quality System Regulation (QSR) 21 CFR 820

Jintronix has been implemented with appropriate design and change controls per Jintronix Inc.'s quality system which is compliant with FDA's Quality System Regulation 21 CFR 820. Standard Operating Procedures relevant to this 510(k) have been referenced herein.

7.9.2 Jintronix Labeling Controls

Jintronix is a prescription use device and various labeling precaution statements further serve as potential device hazard mitigation controls. This includes requiring an in person patient-exercise suitability assessment prior to Jintronix prescription.

[2] Defined as the degree of agreement among repeated administrations of a diagnostic test performed by a single rater

7.10 This summary

- includes only information that is also covered in the body of the 510(k).
- does not contain any puffery or unsubstantiated labeling claims.
- does not contain any raw data, i.e., contains only summary data.
- does not contain any trade secret or confidential commercial information.
- does not contain any patient identification information.